

PUBLIC HEALTH SERVICE

MATERIALS-COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT (CRADA)

This Materials-Cooperative Research and Development Agreement ("MATERIALS-CRADA") has been adopted for use by the National Institutes of Health ("NIH"), the Food and Drug Administration ("FDA"), and the Centers for Disease Control and Prevention ("CDC"), collectively referred to herein as the Public Health Service ("PHS"), for transfers of essential research material ("Research Material") not otherwise reasonably available for PHS research.

1. _____, hereinafter referred to as "Collaborator," agrees to transfer to

PHS's investigator, _____, the following "Research Material":

This MATERIALS-CRADA involves no other exchange of personnel or resources.

2. This Research Material will be used solely in connection with the research plan ("Research Plan"), attached as Appendix A, by PHS's investigator in his/her laboratory under suitable containment conditions.

2(a). Are the Research Materials of human origin? ___ Yes ___ No

2(b). If yes in 2(a), were the Research Materials collected according to 45 CFR Part 46, "Protection of Human Subjects?"

___ Yes (Please provide Assurance Number: _____) ___ No

2(c). Will the Research Materials be used in human subjects?

___ Yes (Please provide Assurance Number: _____) ___ No

3. In all oral presentations or written publications concerning the Research Plan, PHS will acknowledge Collaborator's contribution of this Research Material unless requested otherwise. To the extent permitted by law, PHS agrees to treat in confidence, for a period of three (3) years from the date of the disclosure to the PHS, any of Collaborator's written information about this Research Material that is stamped "CONFIDENTIAL" or any of Collaborator's oral information about this Research Material that is identified in writing as "CONFIDENTIAL" within ten (10) days of the oral disclosure, except for information that was previously known to PHS or that is or becomes publicly available or which is disclosed to PHS without a confidentiality obligation. PHS may publish or otherwise publicly disclose the results of the Research Plan, but if Collaborator has given CONFIDENTIAL information to PHS such public disclosure may be made only after Collaborator has had thirty (30) days to review the proposed disclosure to determine if it contains any CONFIDENTIAL information, except when a shortened time period under court order or the Freedom of Information Act pertains.

4. This Research Material represents a significant investment on the part of Collaborator and is considered proprietary to Collaborator. PHS's investigator therefore agrees to retain control over this Research Material, and further agrees not to transfer the Research Material to other people not under her or his direct supervision without advance written approval of Collaborator. Collaborator reserves the right to distribute the Research Material to others and to use it for its own purposes. When the Research Plan is completed or one (1) year has elapsed, whichever occurs first, or the MATERIALS-CRADA is terminated, the Research Material will be disposed of as directed by Collaborator.

5. This Research Material is provided as a service to the research community. IT IS BEING SUPPLIED TO PHS WITH NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. Collaborator makes no representations that the use of the Research Material will not infringe any patent or proprietary rights of third parties. It is the intention of PHS that Collaborator not be liable for any claims or damages arising from PHS's use of the Research Material; however, no indemnification is provided or intended.

6. The PHS shall promptly report to Collaborator in writing each Subject Invention and any patent applications filed thereon resulting from the research conducted under this MATERIALS-CRADA that is reported to PHS by its employees. Subject Invention means any invention, conceived or first actually reduced to practice in the performance of the research plan during the term of this MATERIALS-CRADA, that is or may be patentable under 35 USC §§101 or 161, protectable under 7 USC §2321, or otherwise protectable by other types of US or foreign intellectual property rights.

7. With respect to Government intellectual property rights to any Subject Invention not made solely by the Collaborator's employees for which a patent or other intellectual property application is filed, PHS hereby grants to the Collaborator an option to elect an exclusive or nonexclusive commercialization license, which is substantially in the form of the appropriate model PHS license agreement. This option does not apply to Subject Inventions conceived prior to the effective date of this MATERIALS-CRADA that are reduced to practice under this MATERIALS-CRADA, if prior to that reduction to practice, PHS has filed a patent application on the Subject Invention and has licensed it or offered to license it to a third party. The terms of the license will fairly reflect the nature of the Subject Invention, the relative contributions of the Parties to the Subject Invention and the MATERIALS-CRADA, the risks incurred by the Collaborator and the costs of subsequent research and development needed to bring the Subject Invention to the marketplace. The field of use of the license will be commensurate with the scope of the research plan.

8. Within three (3) months after PHS provides notice to the Collaborator that the patent or other intellectual property application is filed, the license option must be exercised by written notice mailed to the designated PHS official. Exercise of this option by the Collaborator initiates a license negotiation period that expires nine (9) months after the patent or other intellectual property application filing date. If the last proposal by the Collaborator has not been responded to in writing by PHS within this nine (9) month period, the negotiation period shall be extended to expire one (1) month after PHS so responds, during which month the Collaborator may accept in writing the final license proposal of PHS. In the absence of such acceptance or an extension of the time limits by PHS, PHS will be free to license such intellectual property rights to others. In the event that Collaborator elects the option for an exclusive license, but no such license is executed during the negotiation period, PHS agrees not to make an offer on more favorable terms to third party for a period of six (6) months without first offering Collaborator those more favorable terms. These times may be extended at the sole discretion of PHS upon good cause shown in writing by the Collaborator.

9. Pursuant to 15 USC Section 3710a(b)(1)(A), for inventions made under this MATERIALS-CRADA by a PHS employee(s) or jointly with such employee(s) and employees of the Collaborator, the Government retains a nonexclusive, nontransferable, irrevocable, paid-up license to practice the invention or have the invention practiced throughout the world by or on behalf of the Government. In the exercise of such license, the Government shall not publicly disclose trade secrets or commercial or financial information that is privileged or confidential within the meaning of 5 U.S.C. Section 552(b)(4) or which would be considered as such if it had been obtained from a non-Federal party.

10. Pursuant to 15 USC Section 3710a(b)(2), for inventions made solely by Collaborator employees under this MATERIALS-CRADA, the Collaborator grants to PHS a nonexclusive, nontransferable, irrevocable, paid-up license to practice the invention or have the invention practiced throughout the world by or on behalf of the Government for research or other Government purposes.

11. Pursuant to 15 USC Section 3710a(b)(1)(B), if PHS grants an exclusive license to a Subject Invention made wholly by PHS employees or jointly with a Collaborator under this MATERIALS-CRADA, the Government shall retain the right to require the Collaborator to grant to a responsible applicant a nonexclusive, partially exclusive, or exclusive sublicense to use the invention in Collaborator's licensed field of use on terms that are reasonable under the circumstances; or if the Collaborator fails to grant such a license, to grant the license itself. The exercise of such rights by the Government shall only be in exceptional circumstances and only if the Government determines (i) the action is necessary to meet health or safety needs that are not reasonably satisfied by Collaborator, (ii) the action is necessary to meet requirements for public use specified by Federal regulations, and such requirements are not reasonably satisfied by the Collaborator; or (iii) the Collaborator has failed to comply with an agreement containing provisions described in 15 USC Section 3710a(c)(4)(B). The determination made by the Government under this paragraph is subject to administrative appeal and judicial review under 35 USC §203(2).

12. Any dispute arising under this MATERIALS-CRADA that is not disposed of by agreement of the Principal Investigators shall be submitted jointly to the signatories of this MATERIALS-CRADA. If the signatories are unable to jointly resolve the dispute within thirty (30) days after notification thereof, the Assistant Secretary for Health (or his/her designee or successor) shall propose a resolution. Nothing in this article shall prevent any Party from pursuing any additional administrative remedies that may be available and, after exhaustion of such administrative remedies, pursuing all available judicial remedies.

13. The illegality or invalidity of any provisions of this MATERIALS-CRADA shall not impair, affect or invalidate the other provisions of this MATERIALS-CRADA.

14. Neither this MATERIALS-CRADA nor any rights or obligations of any Party hereunder shall be assigned or otherwise transferred by either Party without the prior written consent of the other Party.

15. All notices pertaining to or required by this MATERIALS-CRADA shall be in writing and shall be signed by an authorized representative and shall be delivered by hand or sent by certified mail, return receipt requested, with postage prepaid, to the addresses indicated on the signature page for each Party. Notices regarding the exercise of license options shall be made pursuant to Article 8. Any Party may change such address by notice given to the other Party in the manner set forth above.

16. By entering into this MATERIALS-CRADA, PHS does not directly or indirectly endorse any product or service provided, or to be provided, whether directly or indirectly related to either this MATERIALS-CRADA or to any patent or other intellectual property license or agreement which implements this MATERIALS-CRADA by its successors, assignees, or licensees. The Collaborator shall not in any way state or imply that this MATERIALS-CRADA is an endorsement of any such product or service by the US Government or any of its organizational units or employees.

17. Either the PHS or the Collaborator may unilaterally terminate this entire Agreement at any time by giving written notice at least thirty (30) days prior to the desired termination date.

18. This MATERIALS-CRADA constitutes the entire agreement between the Parties concerning the subject matter of this MATERIALS-CRADA and supersedes any prior understanding or written or oral agreement.

19. This MATERIALS-CRADA shall be construed in accordance with Federal law as applied by the Federal courts in the District of Columbia.

20. The undersigned expressly certify and affirm that the contents of any respective statements made or reflected in this MATERIALS-CRADA are truthful and accurate.

21. This MATERIALS-CRADA shall be effective upon execution by the Parties. Under the terms of the Federal Technology Transfer Act, PHS has thirty (30) days to disapprove this MATERIALS-CRADA in which case it shall be considered to have never been in effect. The term of this MATERIALS-CRADA is twelve (12) months from execution.

22. The provisions of Articles 3, 5-10, 14 and 20 shall survive the termination of this MATERIALS-CRADA.

Signature Page

FOR PHS:

____ Date _____
Signature of Authorized Official

Printed Name and Title

Mailing Address for Notices:

FOR THE COLLABORATOR:

____ Date _____
Signature of Authorized Official

Printed Name and Title

Mailing Address for Notices:

